DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ketamine Hydrochloride Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Lloyd, Inc. The ANADA provides for veterinary prescription use of ketamine hydrochloride injection in cats for restraint or as an anesthetic and in subhuman primates for restraint.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 W. Thomas Ave., P.O. Box A, Shenandoah, IA 51601–0130, filed ANADA 200–055 that provides for veterinary prescription use of VetaKet™ ketamine hydrochloride injection, intramuscularly, in cats for restraint or as sole anesthetic agent for diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation and in subhuman primates for restraint.

Lloyd, Inc.'s ANADA 200–055 ketamine hydrochloride injection is approved as a generic copy of Fort Dodge Animal Health's NADA 45–290 Vetalar® (ketamine hydrochloride injection). The ANADA is approved as of August 3, 1998, and the regulations are amended in 21 CFR

522.1222a(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers La., rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1222a [Amended]

2. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing ''and 059130'' and by adding in its place ''059130, and 061690.''

Dated: 8/27/98
August 27, 1998

Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

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